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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,023	04/12/2002	Ian L Brown	28053/37955	6243
4743	7590	11/14/2006	EXAMINER	
MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,023

Applicant(s)

BROWN ET AL.

Examiner

Leigh C. Maier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33, 37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2006 has been entered.

Claims 26-33 have been amended. Claims 1-33, 37 and 38 are pending. Claims 11-25 are withdrawn as being drawn to a non-elected invention. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-10 and 26-33 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth in the previous Office action.

Applicant's arguments filed August 28, 2006 have been fully considered but they are not persuasive. In response to this rejection, Applicant has submitted a declaration under 37 CFR 1.132 is insufficient to overcome the rejection of claims as set forth in the last Office action because the reference cited in the specification (Brown) in turn cites Prosky, and these citations would direct one of ordinary skill to the method of measurement (AOAC Method 985.29).

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However, the reference is cited in the specification with respect to the definition of “resistant starch” not the method of measuring said starch. As discussed previously, there are several methods known in the art, and if there are several different ways of calculating a parameter, and the specification fails to indicate which method is to be employed, then the claims are indefinite, *Harrah's Entertainment Inc. v. Station Casinos Inc.*, 71 USPQ2d 1439 (DC Nev 2004).

Claim Rejections - 35 USC § 103

Claims 6, 29 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over KLOR et al (US 5,886,037) in view of WIBERT et al (US 5,776,887) and further in view of SEIB et al (US 5,855,946).

Claim 29 has been amended to require that RS is at least 15% of the total carbohydrate intake.

KLOR teaches a composition for the treatment of obesity and diabetes, as discussed previously.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a composition according to the teaching of KLOR with a resistant starch, such as Novelose, because WIBERT had taught that it is a slowly absorbed carbohydrate and has utility in the preparation of food products. It would be further obvious to administer this composition for the treatment of obesity with a reasonable expectation of success, because KLOR had taught this utility. A product prepared according to KLOR and administered in the amount of about 2000 kcal/day, would provide amylase-resistant starch and unsaturated fat in the

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required amounts. It would be within the scope of the artisan to optimize the amount of RS and unsaturated fat within the ranges disclosed in the art, for the purpose of treating obesity.

Applicant's arguments filed August 28, 2006 have been fully considered but they are not persuasive.

Applicant argues that because "resistant starch has no fewer mono- and disaccharides than does non-resistant starch, this teaching of Klor would not have led to the use of resistant starch," and so "one of ordinary skill ... would not have been motivated to optimize anything with respect to resistant starch." The examiner respectfully disagrees with the characterization of the reference, the content of mono- and disaccharides being beside the point. As discussed previously the cited passage is concerned with the use of a carbohydrate source that is known to give a small rise in plasma lipid or insulin levels. One of ordinary skill, in possession of the cited references would understand that an amount of resistant starch with X% of mono- and disaccharides would, in fact, give a smaller rise in these levels than an amount of non-resistant starch with the same X% of mono- and disaccharides. The artisan would therefore choose the former because of the known desirable properties.

Applicant further argues that Wibert does not teach the use of RS at the levels specified, and "no reason is presented why the person of ordinary skill would choose to modify Klor so as to choose resistant starch levels foreign to Klor in order to treat obesity." The examiner maintains that Klor suggests the use of a carbohydrate with properties as discussed above. Wibert and Seib provide the motivation to use RS because it has the desired property of minimizing blood glucose response, which inherently provides for a lower rise in insulin levels. It would be within the scope of the artisan to optimize the amount of RS (as a percentage of total

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carbohydrate intake) in the diet through routine experimentation with a reasonable expectation of success.

Applicant contends that “Klor’s teaching of a range of 55-95% saturated fat overlaps the claimed range of 10-90% [but] such an incomplete overlap is hardly a teaching to always use less than 90% saturated fat.” (original emphasis) However, such an “always” teaching is not necessary. The reference provides a range within which one of ordinary skill would optimize through routine experimentation.

Again, Applicant states that carbohydrates are “optional” for KLOR compositions, which have very large amounts of saturated fat. The examiner respectfully maintains that this is absolutely not the case. The reference specifically states that “complete foods are preferred” and *exemplifies* a composition of 28-38 wt% fat; 30-50 wt% carbohydrate; and 15-30 wt% protein. See paragraph bridging col 4-5. As previously noted, the reference specifically exemplifies a composition having the required amount of unsaturated fat.

With respect to WIBERT, Applicant contends that this reference is directed to a composition comprising mostly carbohydrates and that it recommends no particular amount of RS starch or motivation to choose unsaturated fat. Again, the particular compositions are not particularly relevant to the rejection, because this reference was used to teach the suitability for using RS in the KLOR composition. However, it is noted that the type of fat used in KLOR is perfectly consistent with what is suggested by WIBERT.

Finally, Applicant notes that SEIB does not teach one to alter the composition of WIBERT to arrive at the instant invention. The examiner agrees, but that was not the reason for

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using SEIB. This reference was used to determine the amount of amylase resistant starch in the product Novelose®.

Claims 1-5, 7-10, 26-28 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over WIBERT et al (US 5,776,887) in view of SEIB et al (US 5,855,946).

WIBERT teaches the preparation of compositions for the use by diabetics and those susceptible to diabetes for controlling blood glucose levels. These compositions comprise slowly absorbed carbohydrates, such as Novelose® (33% RS, as per SEIB) with this carbohydrate being exemplified in several of the embodiments. See col 6, lines 3-17; Example 4; and reference claim 14. The composition of Example 4 comprises about 2.2 g of RS, or 22% of the total carbohydrate content. The fat component in this exemplified product appears to be essentially limited to unsaturated fat.

Applicant argues that only one of Wibert's eight examples disclose a proportion of RS to carbohydrate greater than 15%. First of all, it would be obvious to one of ordinary skill to use and modify *any* of these examples. Because it happens to be one of eight does not make it less obvious. In the absence of unexpected results, it would be within the scope of one of ordinary skill to modify any of the examples within the scope of the teachings of the reference. Applicant has not demonstrated any particular criticality in the use of this particular amount of RS.

Applicant argues that the rejection stating that "those of ordinary skill in the art would have modified the disclosure of Wibert to 'attain adequate energy requirements' so as to fall within the scope of the claims is inappropriate in the absence of some concrete teaching that the reference be so modified. The Wibert reference teaches what it teaches." The examiner agrees,

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and what the reference expressly suggests is the preparation of the composition in an amount to provide a full day's nutrition for a patient. See col 4, lines 45-60. It would certainly be within the scope of the ordinarily skilled practitioner to determine the appropriate calorie level for a diabetic patient. Applicant has demonstrated no criticality in any particular calorie range.

Applicant contends that Wibert sets forth "a laundry list of vegetable and non-vegetable fats ... including many that are primarily saturated including coconut oil, palm kernel oil, milk fat, and egg yolk lipid." The examiner agrees that some (but not a majority – five out of twelve by the examiner's count) of the oils listed are primarily saturated. However, if one were to limit the list to "vegetable oils," the list comprises six primarily unsaturated and three primarily saturated ones. Furthermore, it is noteworthy that most of the examples list "vegetable oil" as the fat component, but two examples, 6 and 7, specifically list "modified palm/palm kernel oil," apparently differentiating that particular fat from "vegetable oil." Therefore, it appears more likely than not that what is used is one of the oils that one more typically associates with the term "vegetable oil," such as corn or soybean, primarily unsaturated fats.

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Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

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Leigh C. Maier

Leigh C. Maier
Primary Examiner
November 8, 2006